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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,941	07/10/2001	Robert A. Henderson	210121.478C17	1153

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
MAUPIN, CHRISTINE L	
ART UNIT	PAPER NUMBER
1637	10

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,941	HENDERSON ET AL.	
	Examiner	Art Unit	
	Christine L. Maupin	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Attached* .

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4 and 17 are drawn to DNA polynucleotides, vectors and host cells compositions classified in class 530, subclass 350+.

II. Claim 2 is drawn to amino acids polypeptide compositions classified in class 530, subclass 300+.

III. Claims 5, 6 and 18 are drawn to isolated antibody compositions, classified in class 530, subclass 387.1+.

IV. Claim 7 is, drawn to methods of polypeptide detection, classified in class 435, subclass 6.

V. Claims 8 and 9 are drawn to a fusion protein compositions, classified in class 435, subclass 69.7.

VI Claims 10 and 16 are drawn to methods of determining the presence of a cancer, classified in class 435, subclass 7.23.

VII. Claims 11 and 12 drawn to methods of making T-cells, classified in class 424, subclass 93.1.

VIII. Claims 14, and 15 are drawn to methods of treatment of a cancer, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Claims 13 and 19 are improperly dependent from multiple claims that are drawn to multiple groups of distinct inventions. Claims 13 and 19 will be examined accordingly

to the extent that applicable in the case the applicant chooses an invention of a group that claims 13 and 19 are dependent from.

The inventions of groups I-III, and V are unrelated. Inventions are unrelated if it can be shown that are as having different modes of operation, different functions, or different effects or inventive groups that are directed to different products (MPEP § 806.05). In the instant case the different inventions of groups I-III are directed to different patentably distinct products that have different physiochemically structures, functions and final end products or out comes. The DNA compositions of group I can be used other than to make the protein compositions of group II such as in gene therapy or as a probe in nucleic acid hybridization assays. The protein of group II may be used in materially different methods than to create the antibody compositions of group III, such as therapeutic or diagnostic method of screening. The fusion protein compositions of group V have different physiochemical structures and functionality characteristics than the protein compositions in-group II, further the DNA compositions of group I would not encode the fusion proteins compositions of group V. The DNA compositions of group I may be obtained by materially different methods than by the antibody composition of group III such as a probe in an immunoassay or immunochromatography or therapeutic methods. Although the DNA encodes a specific protein, such as group II and the protein of group II is the cognate antigen for the production of antibodies of group III, they may also be made from materially different sources such as synthetic chemical synthesis.

The inventions of groups (I-III and V) and the inventions of groups (IV, VI-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA compositions of group I may be used in methods to make proteins. The protein compositions of group II and V may be used in methods to make antibodies or in methods of immunoassays and immunochromatography. The antibodies compositions of the invention of group III may be used in methods of identification of a protein or in methods of identification of a protein agonist without the methods of groups (IV, VI-VIII).

The inventions of groups (IV, VI-VIII) are unrelated. Inventions are unrelated if it can be shown that are as having different modes of operation, different functions, or different effects or inventive groups that are directed to different products (MPEP § 806.05). In the instant case the different inventions of groups (IV, VI-VIII) are directed to different patentably distinct methods that have require different physiochemically structures, different physiochemical functions and have different final outcomes. The invention of the method of group IV requires the expression of a nucleic acid, which is not required for groups VI-VIII. The method of the invention of VI requires the detection of a cancer in a patient, which is not required for groups IV, and VII and VIII. The method of the invention of group VII requires the stimulation of T-cell growth which is not require for the methods of the invention IV, VI and VIII. The method of the invention

of group VIII requires the inhibition of a cancer in patients, which is not required for the methods of groups IV, VI-VIII. The methods of the inventions of groups IV, VI-VIII have distinct elements, which are not required by the other methods of each group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Therefore because these inventions are distinct for the reasons given above and the search required for a single group is not required for a different group, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each group detailed above reads on patentably distinct groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each group. For an elected group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected group drawn to nucleotide sequences, the Applicants are required to elect 1 nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide

sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). This application complies with the requirements of 37 CFR 1.821 through 1.825.

Since the CRF is fully compliant with the above stated rules, the search and examination will proceed once a single species is elected. A fully responsive communication will contain both a proper election of a group, and a single sequence election.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine L. Maupin; whose telephone number is (703) 308-3617 and fax number is (703) 746-7641.

The examiner is normally in the office between the hours of 9:30 a.m. and 5:30 p.m., and telephone calls either in the morning or the mid-afternoon are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the U.S.P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 308-4242 or (703) 308-2724. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

September 11, 2002

Christine L. Maupin
Examiner
Art Unit 1637

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600